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| EXAMINER | |
|---|---|
| TOTH, KAREN E | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/824,776 | LEE ET AL. | |
| | Examiner | Art Unit | |
| | KAREN E. TOTH | 3735 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-76* is/are pending in the application.

4a) Of the above claim(s) *4-7,10,13-16,39-42,44-46 and 48-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8,9,11,12,17-24,26-38,43,47,52-59 and 61-76* is/are rejected.

7)☒ Claim(s) *25, 60* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

2. Claims 1-3, 8, 9, 11, 12, 20-22, 27-38, 43, 47, 53-57, 63, and 65-76 are rejected under 35 U.S.C. 102(e) as being anticipated by Cho (US Patent 6641542).

Regarding claims 1-3 and 8, Cho discloses a method for classifying disordered breathing in a patient comprising detecting a sleep disordered breathing event (column 8, lines 46-48; step 410), sensing motion associated with respiratory effort during the event (column 6, lines 52-54, column 7, lines 19-32, 47-49, and 63-65; step 420), and classifying the event based on the sensed motion (column 6, lines 57-65; column 9, lines 16-19; step 430), where the detection, sensing, and classification are all performed implantably (figures1 and 2; column 3, lines 14-21).

Regarding claim 9, Cho further discloses using respiration patterns to identify disordered breathing events (column 7, lines 33-46).

Regarding claims 11 and 12, Cho further discloses using transthoracic impedance to detect the disordered breathing (column 7, lines 19-32), which is representative of respiratory system conditions.

Regarding claims 20-22 and 26, Cho further discloses identifying and distinguishing between central, obstructive, and mixed disordered breathing (column 6, lines 57-65; column 9, lines 16-19).

Regarding claim 27, Cho further discloses storing information associated with the disordered breathing event (column 8, lines 39-41).

Regarding claim 28, Cho further discloses transmitting information associated with the disordered breathing event (column 4, lines 62-66; column 8, lines 44-45).

Regarding claim 29, Cho further discloses displaying information associated with the disordered breathing event (column 5, lines 46-49).

Regarding claim 30, Cho further discloses using the event's classification to evaluate disordered breathing trends (column 8, lines 52-60).

Regarding claim 31, Cho further discloses delivering therapy to treat disordered breathing based on the classification of the disordered breathing event (step 440).

Regarding claim 32, Cho further discloses modifying a therapy delivered to a patient based on the classification of the disordered breathing event (column 10, lines 14-16).

Regarding claim 33, Cho further discloses the modified therapy being a disordered breathing therapy (column 10, lines 14-22).

Regarding claims 34-37 and 52, Cho discloses a system for classifying disordered breathing comprising a detector configured to detect a disordered breathing event (elements 210, 510-2), a motion sensor configured to sense motion associated with respiratory effort during the event (elements 510, 520), such as chest motion (the

motion of the chest wall changes the impedance values), and a disordered breathing classification processor coupled to the motion sensor and breathing event detector configured to classify the event based on the respiratory event motion (column 5, lines 57-60), where the detector, sensor, and processor may all be configured to be implantable (figures 1, 2).

Regarding claims 38 and 43, Cho further discloses using a transthoracic impedance sensor to sense respiration and respiratory system conditions (element 510-2).

Regarding claim 47, Cho further discloses that the motion sensor may be an accelerometer (column 7, lines 48-49).

Regarding claims 54-57, Cho further discloses the system being configured to identify and distinguish between central, obstructive, and mixed apneas (column 6, lines 57-65; column 9, lines 16-19).

Regarding claim 63, Cho further discloses the system being coupled to a cardiac rhythm management device (column 4, lines 59-62).

Regarding claim 65, Cho further discloses the system being coupled to a patient management system (column 6, lines 16-29).

Regarding claim 66, Cho further discloses a memory coupled to the processor and configured to store information about the disordered breathing event (column 8, lines 39-41).

Regarding claim 67, Cho further discloses a display device coupled to the processor and configured to display information about the disordered breathing event (column 5, lines 46-49).

Regarding claims 68 and 69, Cho further discloses a therapy unit coupled to the processor and configured to deliver or modify therapy to the patient to treat disordered breathing (column 5, lines 16-20; column 10, lines 1-22).

Regarding claim 70, Cho discloses a disordered breathing classification system comprising means for detecting a disordered breathing event (elements 210, 510-2), means for sensing motion associated with respiratory effort during the event (element 520), and means for classifying the disordered breathing event based on the sensed motion (column 5, lines 57-60), where at least part of the system is implantable (figures 1 and 2).

Regarding claim 71, Cho further discloses means for storing information associated with the event (column 8, lines 39-41).

Regarding claim 72, Cho further discloses means for transmitting information associated with the event (column 4, lines 62-66; column 8, lines 44-45).

Regarding claim 73, Cho further discloses means for displaying information associated with the event (column 5, lines 46-49).

Regarding claim 74, Cho further discloses using the event's classification to evaluate disordered breathing event trends (column 8, lines 52-60).

Regarding claims 75 and 76, Cho further discloses means for delivering and/or modifying a therapy delivered to the patient based on the classification of the disordered breathing event (column 5, lines 16-20; column 10, lines 1-22).

***Claim Rejections - 35 USC § 103***

3. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho in view of Burnes (US Patent Application Publication 2003/0195571) and Brydon (US Patent 6547743).

Regarding claims 17 and 18, Cho discloses all the elements of the claimed invention, as disclosed above, except for the respiratory event motion sensing comprising sensing chest wall motion and abdominal motion associated with respiratory effort. Burnes teaches an implantable disordered breathing detection system that utilizes implantable and external sensors to determine and classify disordered breathing episodes (elements 142, 144), in order to obtain a more complete analysis of the patient's condition. Brydon teaches classification of a patient's sleep disordered breathing based on motion and effort signals (figure 7) that are based on chest wall and abdominal motion (figures 2a, 2b; column 13, lines 23-47), in order to accurately determine the type of disordered breathing the patient experiences. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Cho using connections to an external sensor, as taught by Burnes, and used a motion sensor configured to monitor chest wall and/or abdominal effort motions as that

sensor, as taught by Brydon, in order to accurately classify the patient's disordered breathing.

Regarding claims 19 and 61, Cho discloses all the elements of the claimed invention, as disclosed above, except for the respiratory event motion sensing comprising distinguishing between respiratory and non-respiratory motion. Burnes teaches an implantable disordered breathing detection system that utilizes implantable and external sensors to determine and classify disordered breathing episodes (elements 142, 144), in order to obtain a more complete analysis of the patient's condition. Brydon teaches classification of a patient's sleep disordered breathing based on motion and effort signals (figure 7) that can distinguish between respiratory and non-respiratory motion (column 14, lines 33-45), in order to remove artifacts from the effort signal. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Cho using connections to an external sensor, as taught by Burnes, and used a motion sensor configured to distinguish between respiratory and non-respiratory motion, as taught by Brydon, in order to remove artifacts from the effort signal.

Regarding claims 23 and 58, Cho discloses all the elements of the claimed invention, as described above, except for classifying the disordered breathing event as obstructive if the motion associated with respiratory effort is equal to or above a motion threshold. Burnes teaches an implantable disordered breathing detection system that utilizes implantable and external sensors to determine and classify disordered breathing episodes (elements 142, 144), in order to obtain a more complete analysis of the

patient's condition. Brydon teaches classification of a patient's sleep disordered breathing based on motion and effort signals (figure 7) where the breathing is classified as obstructive if the motion signals meet or exceed a particular threshold (column 18, lines 53-59; column 9, lines 11-21), since respiratory effort is characteristic of obstructive apnea events. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Cho using connections to an external sensor, as taught by Burnes, and classified the disordered breathing event as obstructive if the sensed respiratory effort motions met or exceeded a threshold, as taught by Brydon, since respiratory effort is characteristic of obstructive apnea events.

Regarding claims 24 and 59, Cho discloses all the elements of the claimed invention, as disclosed above, except for classifying the disordered breathing event as a central disordered breathing event if motion associated with respiratory effort is below a particular threshold. Burnes teaches an implantable disordered breathing detection system that utilizes implantable and external sensors to determine and classify disordered breathing episodes (elements 142, 144), in order to obtain a more complete analysis of the patient's condition. Brydon teaches classification of a patient's sleep disordered breathing based on motion and effort signals (figure 7) where the disordered breathing is classified as central if a particular effort motion threshold is not met (column 19 line 54 to column 20 line 25), since a lack of effort is characteristic of central apnea events. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Cho using connections to an external sensor, as taught by Burnes, and classified the disordered breathing event as central if the sensed

respiratory effort motions were below a threshold, as taught by Brydon, since a lack of effort is characteristic of central apnea events.

4. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cho in view of Brydon.

Cho discloses all the elements of the claimed invention, as described above, except for at least one of the system components being mechanically coupled to a positive airway pressure device. .Brydon teaches a system that classifies a patient's sleep disordered breathing based on motion and effort signals (figure 7), where the system is mechanically coupled to a PAP device (elements 128, 129; figure 20), in order to provide prompt therapy. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have connected Cho to a PAP device, as taught by Brydon, in order to provide prompt therapy to the patient.

5. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cho in view of Burnes.

Cho discloses all the elements of the claimed invention, as described above, except for the motion sensor and/or breathing detector being wirelessly coupled to the processor. Burnes teaches an implantable disordered breathing detection system that utilizes both implantable and external sensors to determine and classify disordered breathing episodes (elements 142, 144), where the external sensors may be wirelessly connected to the system's processor (paragraph [0034]), in order to obtain a more

complete analysis of the patient's condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the system of Cho with an external, wirelessly connected sensor, as taught by Burnes, in order to obtain a more complete analysis of the patient's condition.

***Allowable Subject Matter***

6. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the method of claim 25, including, *inter-alia*, classifying the disordered breathing event as mixed central and obstructive disordered breathing if the respiratory effort motion is equal to or above a certain threshold for a first portion of the event and below the threshold during a second portion of the event.

The prior art of record fails to anticipate or make obvious the method of claim 60, including, *inter-alia*, classifying a disordered breathing event as obstructive if a motion threshold is met or exceeded during a first portion of the event, and as central if the motion signal is below a motion threshold during a second portion of the event.

Brydon discloses that signals indicative of both central and obstructive events may be expressed simultaneously during mixed apnea events (column 20, lines 43-46), and that a disordered breathing event would be classified as obstructive if a motion

threshold is met or exceeded and as central if the threshold is not met, but does not disclose classifying portions of a single event as either of the two.

Burton (US Patent Application Publication 2007/0032733) discloses a method of classifying mixed central and obstructive disordered breathing events as when periods of both effort and non-effort are present in the respiration signal (paragraph [0510]).

***Response to Arguments***

7. Applicant's arguments filed 10 January 2008 have been fully considered but they are not persuasive.

Regarding the arguments that Cho does not disclose sensing motion, Applicant has analyzed some but not all of the passages cited with that clause. Namely, Applicant has not acknowledged Cho's disclosure of a transthoracic impedance sensor in column 7, which clearly and inherently senses motion associated with respiratory effort, as well as the body movement sensor also cited in column 7 that is described as being used such that "a decrease in the impedance sensor 510 and a low reading from the body movement sensor 520 may indicate the patient has sleep apnea". Such detection is clearly used for Cho's classification, again as cited above.

Regarding Applicant's argument that Cho does not distinguish between central, obstructive, or mixed apneas, the Examiner again disagrees. The cited passage in column 6 shows that apneas and Cheyne-Stokes respiration (CSR) are among the monitored disorders; Cho discloses at column 1, lines 43-44 that CSR is a form of

central sleep apnea. Obstructive sleep apnea, also described in Cho's introduction, corresponds exactly to what Cho monitors with the transthoracic and body movement sensors. And Cho monitors the presence of either or both (mixed) of these types of apneas, disclosed repeatedly, including in previously cited column 9.

Regarding Applicant's argument that Cho does not disclose a processor that classifies disordered breathing events based on respiratory effort motion, the Examiner again disagrees. The cited passage establishes the presence of the processor 310 in the implanted device. Cho also discloses performing diagnostics with the processor (column 9, lines 21-26).

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735